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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,534	10/24/2003	Bernhard Wolf	10051-4U1	9885

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ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/692,534

Applicant(s)

WOLF ET AL.

Examiner

Rosanne Kosson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on August 8, 2005 has been received. The amendments to claims 1-3 and 10 have been entered. Claims 5-9 and 11-12 have been canceled. No claims have been added. Accordingly, claims 1-4 and 10 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicants have explained that the instant application is a divisional of prior Application No. 09/585,146, now U.S. Patent No. 6,656,678, filed on June 1, 2000, because the claims examined in the previous Office action were filed in a preliminary amendment in this prior application. A restriction requirement was issued, and these claims were withdrawn as a non-elected invention. Accordingly, the designation as a divisional is proper.

Claim Rejections - 35 USC § 112

Claims 1-4 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection with respect to the terms "osmotic protective medium" and "separation product" was

Art Unit: 1653

discussed in the previous Office action. This rejection also applies to terms in the amended claims: "bio-components" (broadened from bio-components that carry away surface material), "structure element," and "developing or developed bio-components."

Applicants have not responded to the rejection of "separation product" at all.

Regarding "osmotic protective medium," Applicants allege that this term was not objected to in the prior application. Applicants also allege that claim elements that are defined in terms of their function are equivalent to means plus function claims.

In reply, each application is searched and examined individually and on its own merits, even if a parent application exists. As a result, for the reasons discussed previously, because no osmotic protective media or separation products are named or described in the specification, the claims containing these terms, or depending from claims containing these terms, fail to satisfy the written description requirement.

Regarding means plus function claims, Applicants have not indicated which claims they consider to be means plus function claims. Means plus function claims are rare to nonexistent in biotechnology, because biomolecules, even within one type, such as proteins, vary so widely in their biological, chemical and physical properties, that terms analogous to "a means for opening a door" would be very difficult to find and claim. Nevertheless, with or without means plus function labels, the amended claims are not adequately described so that one of skill in the art of coupling biomolecules to semiconductor wafers would understand what the claimed invention is.

With respect to the terms "bio-components," "structure element," and "developing" or "developed" bio-components, these are not adequately described.

Art Unit: 1653

Although the genus of bio-components is discussed in the specification, there is no evidence that any representative species of such a large and varied genus was in the possession of the inventors at the time of filing. The specification notes on pp. 2-3 that a bio-component is a cell, organelle, biomolecule or micelle. The most specific information in the specification is that the bio-component is some type of highly surface-selective tumor cell, although none are named, or LS 174T cells. The specification does not describe how these cells are attached to semiconductor wafers. The specification also does not describe the nutrient media and osmotic protective media to be used with these cells. To be complete, the specification must provide this information. Stating that one of skill in the art could search the literature to find the missing information does not make the specification complete. The specification notes that the bio-components develop into different forms- different colors, shapes and sizes, depending on the topography and chemical composition of the surface layer, but such a development is not described. What chemical composition and what topography cause the bio-component to develop different colors, shapes and sizes? How does this development occur? The term "structure element" does not appear in the specification. Thus, this term is not described.

Further, with respect to "structure element," this term is new matter. The claims are rejected for reciting new matter.

To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical

Art Unit: 1653

characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. The specification does not disclose any specific representative species of bio-components, apart from LS 174T cells, differently developed bio-components, or structure elements, with or without identifying characteristics. Therefore, the claims fail to satisfy the written description requirement.

Claims 1-4 and 10 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection with respect to the terms "osmotic protective medium" and "separation product" was discussed in the previous Office action. This rejection also applies to terms in the amended claims: "bio-components" (broadened from bio-components that carry away surface material), "structure element," and "developing or developed bio-components."

As a result, the scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to determine which specific bio-components may be attached to a semiconductor wafer to structure it, how the bio-components develop differently as a function of surface chemical composition and topography, how the surface of the wafer is structured by attaching

Art Unit: 1653

bio-components (If a bio-component can be made to adhere to the surface of a semiconductor wafer, that adherence does not change the wafer or the bio-component. Applicants have not shown that, or indicated in what way, adherence to the wafer changes the bio-component.), what a structure element is, and how the developed bio-components are used as structure elements.

To elaborate, for example, Gilardi et al. ("Manipulating redox systems: application to nanotechnology," Trends in Biotechnology 19(11):468-476, 2001) disclose that proteins may be immobilized on semi conductive and conductive surfaces in a variety of ways, physical adsorption, inclusion in conducting polymers, inclusion in self-assembled monolayers, oriented or non-oriented attachment to self-assembled monolayers and direct site-specific attachment (see p. 473). None of these methods changes the structure of the proteins or the surfaces to which they are attached. Because of their publication date, Gilardi et al. are not prior art. But their teachings reflect the state of the art at the time of Applicants' invention, as this fact has not changed since Applicants' filing date or priority date.

Applicants' specification does not teach that merely by attaching a bio-component to a semiconductor wafer, a differentially developed bio-component is formed, and it is therefore used as structure element, and it therefore structures the surface. If this were true, many publications would anticipate the claimed invention, including those submitted by Applicants, e.g., Clark et al. (US 4,728,591) and Hollenberg et al. (EP 491059).

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary (immense, because Applicants assert that the surface layer of a semiconductor wafer may be structured by attaching bio-components, developing them, using them as structure elements, and separating out a separation product from the surface, without naming the bio-components or the separation product or indicating how the bio-components are developed, how they are used as structure elements, or how a separation product is separated from the surface of the wafer), (2) the amount of direction or guidance presented (none, apart from the disclosure that LS 174T cells may be attached to semiconductor wafers), (3) the presence or absence of working examples (no working or prophetic examples appear in the specification), (4) the nature of the invention (a process for structuring the surface layer of a semiconductor wafer comprising applying bio-components, differentially developing the bio-components, and

Art Unit: 1653

using the differentially developed bio-components as a structure element, which process structures the surface layer, is claimed), (5) the state of the prior art (semiconductor wafers to which DNA is attached as a designed mask for producing a microcircuit pattern or to which proteins are attached to convert light energy to electrical energy are known, see below, but these do not disclose the steps of differential development, using the differentially developed bio-components as a structure element to structure the surface layer, or separating a separation product from the surface layer), (6) the relative skill of those in the art (very high, that of highly trained research scientist), (7) the predictability or unpredictability of the art (see below), and (8) the breadth of the claims (broad, as discussed above).

With respect to the quantity of experimentation necessary, to demonstrate that any bio-components may be attached to the surface of a semiconductor wafer, differentially developed as a function of the nature of the surface layer, and used as a structure element, thereby structuring the surface layer, many experiments would have to be conducted. The results of the experiments would have to show that many very different types of bio-components adhere to the surface of semiconductor wafers, that these bio-components develop in some way and develop differently, the differential development caused and affected by the chemical composition or topography of the surface layer (one of skill in the art would also have to determine what development is and create a procedure that achieves development), and that the differently developed bio-components are used as structure elements to structure the surface layer.

Art Unit: 1653

Such experimentation is necessary because the specification discloses none of this information. There is a large gap between Applicants' disclosure and Applicants' method as claimed, which is claimed broadly. One of skill in the art would have to experiment unduly to fill in this gap.

To be commensurate in scope with broad claims for a process for structuring the surface layer of a semiconductor wafer, comprising applying any bio-components, differentially developing the bio-components, and using the differentially developed bio-components as a structure element to structure the surface layer, a great deal of guidance must be present in the specification to enable one of skill in the art to practice this method. As noted above, no examples are disclosed.

Regarding predictability, as noted above, specific bio-components apart from LS 174T cells are not disclosed. Biotechnology is one of the unpredictable arts, as each biomolecule or cell has different biological, physical and chemical properties and reacts differently. Therefore, one of skill in the art could not predict, given the instant specification, that the surface of a semiconductor wafer may be structured by applying bio-components, developing them differently and using them as structure elements.

Moreover, what Applicants' intended to teach with respect to restructuring the surface of a semiconductor wafer is not at all clear from the instant specification or claims. They have not taught how to make and use the claimed invention.

Regarding the enablement rejections in the previous Office action, Applicants have not responded specifically, but assert that these rejections are overcome because most of the terms indicated as not adequately described in the written description

Art Unit: 1653

rejections have been removed. In reply, this response does not serve to overcome the enablement rejections. Applicants have not explained how the claimed invention is enabled.

Accordingly, claims 1-4 and 10 fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 102

In view of Applicants' amendments to the claims, the rejections under 35 U.S.C. 102(b) are withdrawn.

The following references are cited, or were cited by Applicants, to show further the state of the art. Hollenberg et al. (EP 491059) disclose that DNA may be bound to the surface of semiconductor wafers and designed networks created, based on the specific sequences in the DNA used. These networks may be used as masks for creating patterns (see Example 5, pp. 7-8) or as microelectronic switches, because certain DNA binding proteins bind only under certain electronic conditions in the DNA strands, thereby creating a switching element (See Example 1, pp. 5-6).

Clark et al. (US 4,728,591) disclose nanoscale arrays, and methods of making these arrays, in which a protein is attached to a semiconductor wafer (10). Holes are present in the protein layer (12), and the protein layer may be covered with a non-conductive or conductive layer (14) having holes aligned with those in the protein layer (see col. 4, line 23, to col. 8, line 7, and Figs. 1 and 3). Material may be removed from the semiconductor wafer (22) by reaction with a reagent that penetrates through the holes in the protein layer. The reagent may be activated by light that penetrates

Art Unit: 1653

through the holes. The removal of material may also occur by electrical conduction of ions through the channels in the protein layer (see col. 8; line 60, to col. 9, line 12).

Miyasaka et al. (Science 255(5042):342-344, 1992) also disclose a device, and a method for making the device, in which proteins are attached to a semiconductor wafer, a hybrid photoactive device for converting light irradiation to electric current, in which fragments of chlorosome-containing bacterial membranes are applied as a series of monolayer films onto a transparent tin oxide semiconductor layer. The chlorosome-containing film and semiconductor layer are then sandwiched in glass and connected to a photocurrent output, so that light is efficiently absorbed and transmitted. The protein is immersed in an aqueous electrolyte solution (see p. 342, last paragraph, and p. 343).

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1653

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

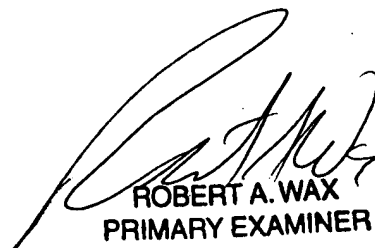
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1653

rk2005-08-31



ROBERT A. WAX
PRIMARY EXAMINER